# S. 2472

To require the Administrator of the Environmental Protection Agency to issue rules governing risk assessments, and for other purposes.

#### IN THE SENATE OF THE UNITED STATES

September 28 (legislative day, September 12), 1994

Mr. Lott introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

# A BILL

To require the Administrator of the Environmental Protection Agency to issue rules governing risk assessments, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Sound Science in Risk
- 5 Assessment Act".
- 6 SEC. 2. FINDINGS.
- 7 Congress finds that—
- 8 (1) as of the date of enactment of this Act, ap-
- 9 proximately \$140,000,000,000 per year, over 2 per-
- cent of the annual gross national product of the

- United States, is being spent on environmental compliance, and the amount being spent is expected to rise substantially;
  - (2) unfunded Federal environmental mandates are straining the budgets of State and local governments and may diminish the financial resources available for other important public programs and services;
  - (3) an environmental risk assessment developed by the Environmental Protection Agency is often perceived as not containing sufficient scientific objectivity, absence of bias, clarity, or consistency to serve as a sound and credible basis for protecting public health and safety, determining environmental protection needs and priorities, making regulatory decisions, or allocating limited financial resources; and
  - (4) Executive Order No. 12866 (5 U.S.C. 601 note; relating to regulatory planning and review) requires a decision by a Federal agency to be based on the best reasonably obtainable scientific and technical information, and embodies the principle of openness in government.

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## 1 SEC. 3. RISK ASSESSMENT PRINCIPLES.

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2	In accordance with this Act, the Administrator of the
3	Environmental Protection Agency (referred to in this Act
4	as the "Administrator") shall develop rules, proposed
5	rules, and review procedures that provide that—
6	(1) risk assessments shall be—
7	(A) consistent;
8	(B) of high technical quality;
9	(C) scientifically objective; and
10	(D) unbiased; and
11	(2) significant uncertainties regarding facts,
12	scientific knowledge, the validity of analytical tech-
13	niques, or numerical risk estimates are clearly dis-
14	closed in terms readily understandable to the public.
15	SEC. 4. PROPOSED RULES.
16	(a) Proposed General Rules.—Not later than
17	180 days after the date of enactment of this Act, the Ad-
18	ministrator shall issue, in accordance with section 3, pro-
19	posed rules that—
20	(1) set forth uniform general procedures gov-
21	erning risk assessments conducted by the Environ-
22	mental Protection Agency; and
23	(2) incorporate, to the extent the Administrator
24	considers advisable, relevant guidelines existing prior
25	to the issuance of the proposed rules.

- 1 (b) Distinctive Approaches, Techniques, or 2 Methodologies.—
- (1) Proposed distinctive rules.—Not later than 1 year after the date of enactment of this Act, the Administrator shall issue, in accordance with section 3, proposed rules to govern use of a distinc-tive type of risk assessment approach, technique, or methodology. The rules shall specify the minimum standard for a risk assessment approach that is appropriate for the scale of the problem to be assessed, the level of scientific understanding, and the available data.
  - (2) USE OF DISTINCTIVE APPROACHES, TECHNIQUES, OR METHODOLOGIES.—In accordance with section 3, the Administrator shall determine the distinctive types of risk assessment approaches, techniques, or methodologies for which a proposed rule will be issued pursuant to paragraph (1). The Administrator shall include risk assessment approaches, techniques, or methodologies that utilize epidemiological data. In the case of an approach, a technique, or a methodology not in use prior to the date of enactment of this Act, the Administrator shall develop rules to govern the distinctive use of the approach, technique, or methodology before using the ap-

1	proach, technique, or methodology in a risk assess-
2	ment.
3	SEC. 5. RISK ASSESSMENT REVIEW.
4	(a) REVIEW PROCEDURES.—Not later than 180 days
5	after the date of enactment of this Act, the Administrator
6	shall issue procedures, in accordance with section 3, for
7	the review and revision of a risk assessment completed
8	prior to the enactment of this Act or the issuance of final
9	risk assessment rules under section 6.
10	(b) Basis for Review.—
11	(1) Criteria for review.—A review of a risk
12	assessment in accordance with the procedures issued
13	under subsection (a) shall be conducted by the Ad-
14	ministrator on the written petition of a person if—
15	(A) the risk assessment is inconsistent
16	with the principles set forth in section 3;
17	(B) the risk assessment is inconsistent
18	with a rule issued under section 4; or
19	(C) the risk assessment does not take into
20	account significant new scientific data or sci-
21	entific understanding.
22	(2) Response to Petition.—Not later than
23	60 days after receiving a petition under paragraph
24	(1), the Administrator shall respond to the petition
25	by agreeing or declining to review the risk assess-

- 1 ment referred to in the petition, and shall state the
- 2 basis for the decision.
- 3 (3) JUDICIAL REVIEW.—Denial of a petition by
- 4 the Administrator shall be subject to judicial review
- 5 in accordance with chapter 7 of title 5, United
- 6 States Code.

#### 7 SEC. 6. FINAL RULES.

- 8 (a) Notice and Comment Procedures.—Not later
- 9 than 270 days after the date of enactment of this Act,
- 10 in accordance with section 553 of title 5, United States
- 11 Code, the Administrator shall publish in the Federal Reg-
- 12 ister a list of risk assessment approaches, techniques, or
- 13 methodologies for which a rule shall be issued under sub-
- 14 section (b), after taking into account comments by the
- 15 public, Federal agencies, States, municipalities, experts in
- 16 the scientific community, and such other persons as the
- 17 Administrator considers advisable.
- 18 (b) Issuance of Final Rules.—Not later than 1
- 19 year after the date of enactment of this Act, in accordance
- 20 with sections 3 and 4 of this Act and section 553 of title
- 21 5, United States Code, the Administrator shall publish in
- 22 the Federal Register final rules, after taking into account
- 23 comments by the public, Federal agencies, States, munici-
- 24 palities, experts in the scientific community, and such
- 25 other persons as the Administrator considers advisable.

### 1 SEC. 7. PRIVATE RIGHTS OF ACTION PRECLUDED.

- 2 Nothing in this Act shall give rise to a private right
- 3 of action seeking damages against the United States or

4 against an agency or instrumentality of the United States.

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